



DEPARTMENT OF HEALTH AND HUMAN SERVICES

91149d  
Food and Drug Administration  
Seattle District  
Pacific Region  
22201 23rd Drive SE  
Bothell, WA 98021-4421

Telephone: 425-486-8788  
FAX: 425-483-4996

April 18, 2001

**VIA CERTIFIED MAIL  
RETURN RECEIPT REQUESTED**

In reply refer to Warning Letter SEA 01-38

Mr. Jack Mercer, President  
Starfish Sea Products, Inc.  
4250 8<sup>th</sup> Avenue NW  
Seattle, Washington 98107

**WARNING LETTER**

Dear Mr. Mercer:

On January 23, 2001, George F. Long conducted an inspection of your firm. The inspection was conducted to determine your firm's compliance with FDA's seafood processing regulations [21 Code of Federal Regulations (CFR) 123]. The seafood processing regulations, which became effective on December 18, 1997, require that you have and implement written verification procedures to verify that your foreign suppliers have implemented a preventive system of food safety controls known as Hazard Analysis Critical Control Point (HACCP) in accordance with U.S. requirements.

The products covered during this inspection were battered halibut and battered cod imported from [REDACTED]. At the conclusion of that inspection a list of violations (Form FDA 483) was presented to Ms. Valerie Davies, Operations Manager. These HACCP violations cause your imported products to be adulterated within the meaning of 402(a)(4) of the Federal Food, Drug, and Cosmetic Act. Specifically,

**You must implement an affirmative step which ensures that the fish and fishery product(s) you import are processed in accordance with the seafood HACCP regulation in order to comply with 21 CFR 123.12(a)(2)(ii). However, your firm did not perform an affirmative step for battered cod fillets manufactured by [REDACTED]**

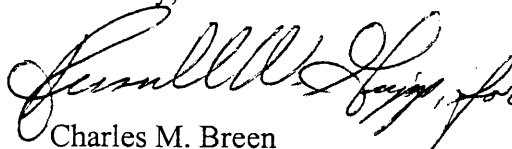
The above HACCP violations are not meant to be an all-inclusive list of deficiencies at your firm. It is your responsibility to assure that all of your products are in compliance with applicable statutes enforced by the FDA. You should take prompt action to correct all of the HACCP violations. Failure to promptly correct these violations may result in regulatory action without further notice such as seizure and/or injunction. Furthermore, your firm and the foreign

Mr. Jack Mercer, President  
Starfish Sea Products, Inc., Seattle, Washington  
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processor may be placed on import alert and future shipments of the product may be subject to detention without physical exam.

You should notify this office in writing, within 15 working days of the receipt of this letter, of the specific steps you have taken to correct the noted violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. Please send your reply to the Food and Drug Administration, Attention: Thomas S. Piekarski, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021. If you have questions regarding any issue in this letter, please contact Thomas Piekarski at (425) 483-4975.

Sincerely,

A handwritten signature in cursive script, appearing to read "Charles M. Breen", written in dark ink.

Charles M. Breen  
District Director

Enclosure:

Form FDA 483